Citation:

Pittaway JK, Robertson IK, Ball MJ. Chickpeas may influence fatty acid and fiber intake in an ad libitum diet, leading to small improvements in serum lipid profile and glycemic control. *J Am Diet Assoc.* 2008 Jun;108(6):1009-13.

PubMed ID: <u>18502235</u>

Study Design:

Ordered Crossover Trial

Class:

C - <u>Click here</u> for explanation of classification scheme.

Research Design and Implementation Rating:



POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To observe the effects of chickpea supplementation on ad libitum nutrient intake, body weight, serum lipids, lipoproteins and other metabolic changes.

Inclusion Criteria:

- Adults age 30 to 70 years old during September to November 2004
- Not taking medication for hypoglycemia or hyperlipidemia
- Cardiovascular disease (CVD) risk factors associated with dyslipidemia
- Poor glucose tolerance
- Family history of heart disease, type 2 diabetes or CVD risk factors.

Exclusion Criteria:

None specifically mentioned.

Description of Study Protocol:

Recruitment: Subjects were recruited via local posters, radio and newspaper articles from September to November 2004.

Design: Ordered crossover trial

- 4 week "familiarization" period with normal intake
- 12 week ad libitum diet with chickpeas
- 4 week normal intake

Blinding used (if applicable): not specified

Intervention:

During the chickpea diet phase, subjects were asked to consume an average minimum of 104 grams of chickpeas per day as part of their ad libitum diet.

Statistical Analysis:

- Sample size calculation
- Repeated measures analysis of variance using general linear modelling
- STATA Statistical Data Analysis software (version8.2, January 2003, Statacorp, College Station, TX)

Data Collection Summary:

Timing of Measurements

- Study completed from September 2004 to May 2005
- Included 4 weeks Usual Diet, 12 weeks Chickpea Diet and 4 weeks Usual diet.
- Venous blood samples and weighed diet records were conducted during the final week of each diet phase.

Dependent Variables

- Total cholesterol
- Triacylglycerols
- HDL cholesterol
- Glucose
- Insulin
- LDL cholesterol
- Homeostasis assessment model of insulin resistance (HOMA-IR)
- Body weight

Independent Variables

• Diet consumed including amount of chickpea consumed and time

Control Variables

• Subjects served as own controls in crossover design.

Description of Actual Data Sample:

Initial N: 50

Attrition (final N): 45 (13 premenopausal women, 19 postmenopausal women, 13 men)

Age: 52.2 ± 6.1 years

Ethnicity: not specified

Other relevant demographics:

- Mean fasting serum total cholesterol 250 ± 54 mg/d,
- Mean fasting plasma glucose 89.2 ± 18.0 mg/dL,
- Mean fasting plasma insulin $6.25 \pm 4.29 \,\mu\text{IU/mL}$ and
- Fasting HOMA-IR of 1.45 <u>+</u> 1.34

Anthropometrics:

• Mean Weight 74.7 + 16.0 kg

• Mean Body Mass Index (BMI) $26.3 \pm 4.8 \text{ kg/m}^2$

Location: Tasmania, Australia

Summary of Results:

Key Findings

- Incorporating chickpeas in diet significantly increased dietary fiber and energy from protein while decreasing energy supplied from saturated fat.
- In the chickpea phase, mean dietary fiber intake was 6.77 g/day more and mean polyunsaturated fatty acid consumption (as a percentage of total fat) was 2.66% (both P < 0.001), causing the polyunsaturated to saturated fatty acids ratio to change from 0.39 to 0.47 (P = 0.045).
- Serum total cholesterol and LDL cholesterol were 7.7 mg/dL (0.20 mmol/L) and 7.3 mg/dL (0.19 mmol/L) less, respectively, after the chickpea phase (P < 0.01), fasting insulin was 0.75 μ IU/mL (5.21 pmol/L) less (P = 0.045) and the HOMA was 0.21 less (P = 0.01).
- Dietary fiber had the greatest single effect, reducing serum total cholesterol by 15.8 mg/dL (0.41 mmol/L, P = 0.01).
- For every 1 standard deviation increase of chickpea consumption, there was a 0.57 percentage of energy from protein increase and a 3.40 gram increase of dietary fiber.
- Serum total cholesterol, LDL cholesterol, fasting insulin and HOMA-IR all decreased significantly during the chickpea phase.
- Polyunsaturated and saturated fatty acids had equivalent but opposing effects on serum total cholesterol and insulin
- A small, nonsignficiant decrease in mean body weight was observed during the chickpea compared with the usual phase (0.45 kg; 95% CI: -0.87, 0.03 kg; P=0.07).

| | TC Mean Difference | TC 95% CI | TC P value | Insulin Mean Difference | Insulin 95% CI | Insulin P value |
|---|--------------------------|------------------|------------------|-------------------------------|-------------------|--------------------|
| Chickpea - Usual Intake | -7.7 | -12.7 to -2.3 | 0.01 | -0.89 | -1.64 to -0.14 | 0.02 |
| Dietary Fiber (g) (25.89 <u>+</u> 8.02) | -15.8 | -28.2 to -3.5 | 0.01 | 0.33 | -1.53 to 2.19 | 0.73 |
| SFA %TF (42.57 <u>+</u> 7.15) | 10.0 | 0.0 to 20.1 | 0.046 | 0.75 | 0.17 to 1.33 | 0.01 |
| PUFA %TF (17.31±5.21) | -11.6 | -20.5 to -3.1 | 0.01 | -0.70 | -1.31 to -0.10 | 0.02 |
| Protein %Energy (17.96±2.85) | 4.6 | -58 to 15.0 | 0.38 | -0.51 | -1.05 to 0.04 | 0.07 |

TC = Total Cholesterol (mg/dL), Insulin (μ IU/mL), CI = Confidence Interval, SFA %TF = Saturated Fatty Acids as percentage of total fats, PUFA %TF = Polyunsaturated Fatty Acids as percentage of total fats, Protein %E = protein as percentage of total energy intake

Author Conclusion:

Incorporating chickpeas in the ad libitum intake of healthy adults resulted in a small but significantly increased mean polyunsaturated fatty acid (PUFA) and dietary fiber intake and polyunsaturated to saturated fatty acid ratio that was associated with reduced serum total cholesterol, fasting insulin concentration and Homeostasis Assessment Model of Insulin Resistance (HOMA-IR).

Reviewer Comments:

Strengths: subjects consumed full amount of study protocol, measured intake

Weakness: potential concern of commodity group funding and donated chickpeas

Research Design and Implementation Criteria Checklist: Primary Research

| Relevance | Onections |
|-----------|-----------|
| Refevance | Questions |

| 1. | Would implementing the studied intervention or procedure (if found |
|----|--|
| | successful) result in improved outcomes for the |
| | patients/clients/population group? (Not Applicable for some |
| | epidemiological studies) |

2. Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?

3. Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?

4. Is the intervention or procedure feasible? (NA for some epidemiological studies)

Validity Questions

3.

| 1. | Was the res | earch question clearly stated? | Yes |
|----|--|---|-----|
| | 1.1. | Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified? | Yes |
| | 1.2. | Was (were) the outcome(s) [dependent variable(s)] clearly indicated? | Yes |
| | 1.3. | Were the target population and setting specified? | Yes |
| 2. | Was the selection of study subjects/patients free from bias? | | Yes |
| | 2.1. | Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study? | Yes |
| | 2.2. | Were criteria applied equally to all study groups? | Yes |
| | 2.3. | Were health, demographics, and other characteristics of subjects described? | Yes |
| | 2.4. | Were the subjects/patients a representative sample of the relevant population? | Yes |

Were study groups comparable?

| | 3.1. | Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT) | N/A |
|----|--------------|--|-----|
| | 3.2. | Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline? | Yes |
| | 3.3. | Were concurrent controls used? (Concurrent preferred over historical controls.) | Yes |
| | 3.4. | If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis? | N/A |
| | 3.5. | If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.) | N/A |
| | 3.6. | If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")? | N/A |
| 4. | Was method | of handling withdrawals described? | Yes |
| | 4.1. | Were follow-up methods described and the same for all groups? | Yes |
| | 4.2. | Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.) | Yes |
| | 4.3. | Were all enrolled subjects/patients (in the original sample) accounted for? | Yes |
| | 4.4. | Were reasons for withdrawals similar across groups? | Yes |
| | 4.5. | If diagnostic test, was decision to perform reference test not dependent on results of test under study? | N/A |
| 5. | Was blinding | used to prevent introduction of bias? | Yes |
| | 5.1. | In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate? | No |
| | 5.2. | Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.) | Yes |
| | 5.3. | In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded? | N/A |
| | 5.4. | In case control study, was case definition explicit and case ascertainment not influenced by exposure status? | N/A |
| | 5.5. | In diagnostic study, were test results blinded to patient history and other test results? | N/A |
| 6. | | ntion/therapeutic regimens/exposure factor or procedure and any | Yes |
| | 6.1. | In RCT or other intervention trial, were protocols described for all regimens studied? | Yes |

| sufficient to produce a meaningful effect? 6.4. Was the amount of exposure and, if relevant, subject/patient compliance measured? 6.5. Were co-interventions (e.g., ancillary treatments, other therapies) described? 6.6. Were extra or unplanned treatments described? 6.7. Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups? 6.8. In diagnostic study, were details of test administration and replication sufficient? 7. Were outcomes clearly defined and the measurements valid and reliable? 7.1. Were primary and secondary endpoints described and relevant to the question? 7.2. Were nutrition measures appropriate to question and outcomes of concern? 7.3. Was the period of follow-up long enough for important outcome(s) to occur? 7.4. Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures? 7.5. Was the measurement of effect at an appropriate level of precision? 7.6. Were other factors accounted for (measured) that could affect outcomes? 7.7. Were the measurements conducted consistently across groups? 8. Was the statistical analysis appropriate for the study design and type of outcome indicators? 8.1. Were statistical analyses adequately described and the results reported appropriately? 8.2. Were correct statistical tests used and assumptions of test not violated? 8.3. Were statistics reported with levels of significance and/or confidence intervals? 8.4. Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)? 8.5. Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)? 8.6. Was clinical significance as well as statistical significance reported? 8.7. If negative findings, was a power calculation reported to address type 2 | | 6.2. | In observational study, were interventions, study settings, and clinicians/provider described? | N/A |
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| 8.7. If negative findings, was a power calculation reported to address type 2 | | 8.5. | 1 0 | Yes |
| | | 8.6. | Was clinical significance as well as statistical significance reported? | Yes |
| | | 8.7. | If negative findings, was a power calculation reported to address type 2 error? | Yes |

| 9. | Are conclusion consideration | ons supported by results with biases and limitations taken into n? | Yes |
|-----|---|--|-----|
| | 9.1. | Is there a discussion of findings? | Yes |
| | 9.2. | Are biases and study limitations identified and discussed? | Yes |
| 10. | Is bias due to study's funding or sponsorship unlikely? | | ??? |
| | 10.1. | Were sources of funding and investigators' affiliations described? | Yes |
| | 10.2. | Was the study free from apparent conflict of interest? | ??? |

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